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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,459	05/02/2005	Curtis C. Harris	63139(47992)	3076
46037 7590 09/18/2009 EDWARDS ANGELL PALMER & DODGE LLP PO BOX 55874 BOSTON, MA 02205				
EXAMINER				
QIAN, CELINE X				
ART UNIT		PAPER NUMBER		
1636				
MAIL DATE		DELIVERY MODE		
09/18/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/533,459

**Applicant(s)**

HARRIS ET AL.

**Examiner**

CELINE X. QIAN

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 May 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-29 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 20-29 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 20-29 are pending in the application.

This Office Action is in response to the amendment filed on 5/19/09.

***Response to Amendment***

Acknowledgement is made of Applicant's reply to the information requirement under 37 CFR 1.105.

***Election/Restrictions***

Applicants assert that it is unclear what claims has been rejoined or rejected. The examiner clarify that the statement claims 1-19 and 29-31 has been withdrawn from consideration is mistaken because claim 29 was inadvertently included. Claim 29 has been examined in the previous office action.

***Claim Rejections***

The rejection of claim 29 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of the amendment.

The rejection of claims 20-28 under 35 U.S.C. 102 (a) and (b) has been withdrawn in light of the amendment.

***New Grounds of Rejection Necessitated by Amendment***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Erlander et al (US 2004/0002067).

Erlander et al. disclose a microarray chip obtained by using 11,435 clones from the IMAGE consortium (see page 8, [0093]). Erlander et al. disclose that the microarray comprises genes including GGH and KIAA0469 (see page 32, Table 3, line 14 from bottom, and page 72, Table 7, line 17 from bottom). Claim 28 and 29 recites “one or more genes selected from the group consisting of C5, CPE...GGH...” (28) and “one or more genes selected from the group consisting of GGH and CPE”(29). It is unclear whether the claim intends to encompass one or more genes in addition to GGH or one or more genes including GGH because GGH is in the listed choices. In the instant case, it is interpreted that these claims is directed to a microarray comprising one or more genes in the list including GGH. Although the chip disclosed in Erlander et al. is not used to identify genes differentially expressed in different types of neuroendocrine tumor, it nevertheless meets the limitation of a microarray comprises genes distinguishably arrayed in spaced apart regions and comprises more than 10 genes, wherein said genes or polynucleotide fragments or RNA transcripts includes GGH, or a polynucleotide fragment or RNA transcript thereof. The implied use of the microarray chip does not impart a structural difference between the claimed microarray and what is disclosed in the Erlander et al. Therefore, this reference anticipates the instantly claimed invention.

Claims 20-29 are rejected under 35 U.S.C. 102(c) as being anticipated by Haab et al (US 2006/0088823).

Haab et al. disclose producing a microarray comprising 21,632 cDNA from a bacterial library (see page 12, [0144]). Haab et al. disclose that one of the genes included is GGH (see page 19, [0169] no. 31 of Table 5). As discussed above, Although the chip disclosed in Erlander et al. is not used to identify genes differentially expressed in different types of neuroendocrine tumor, it nevertheless meets the limitation of a microarray comprises genes distinguishably arrayed in spaced apart regions and comprises more than 10 genes, wherein said genes or polynucleotide fragments or RNA transcripts includes GGH, or a polynucleotide fragment or RNA transcript thereof. The implied use of the microarray chip does not impart a structural difference between the claimed microarray and what is disclosed in the Haab et al. Therefore, this reference anticipates the instantly claimed invention.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 28 and 29, the recitation of "the microarray of claim 20/28, wherein ... include one or more genes selected from the group consisting of ...GGH..." renders the claims indefinite because it is unclear whether these claims intends to encompass one or more genes in

addition to GGH or including GGH because GGH is already recited in claim 20. As such, the metes and bounds of the claim cannot be established.

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /  
Primary Examiner, Art Unit 1636